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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,573	09/23/2003	Jonathan R. Coppeta	17509-0068	3038

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ATLANTA, GA 30309

EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/668,573

Applicant(s)

COPPETA ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-29, 35, 36 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-29, 35, 36, and 39-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is in response to applicant's amendments submitted 2 January 2007.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14-20, 22-29, 35, 36, 39, and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al (US 7,025,323) in view of Santini Jr et al (US 5,797,898).

Krulevitch teaches an array of discrete microtubes (97) defining a reservoir (86-90), a release formulation (103), and means for dispensing the release formulation (81-85) by positive displacement of a barrier material (98-102) by an expanding material (81-85) by application of heat from a resistive heating element (81'-85'). See Figs 7A and 7B.

Krulevitch does not disclose the material of the microneedles being made of a metal, or a rupturable metal foil covering over the distal end of the microneedles.

Santini discloses a microreservoir array which is covered by a metal foil where the array is made of a biocompatible material (copper or gold, for example). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a metallic cover over the microneedles in order to prevent leakage of the reservoirs or contamination of the reservoir contents. Regarding claim 20, copper is considered "reactive." Regarding the defects to facilitate rupture, the bonding of the metal layer

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would inherently create stress concentrations in the metal foil along the edge of the microneedle. Claim 28 is a product by process claim which is given little patentable weight.

3. Claims 14-20, 22-29, 35, 36, 39, and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al (US 7,025,323) in view of Gonnelli (US 2003/0135201)

Krulevitch teaches an array of discrete microtubes (97) defining a reservoir (86-90), a release formulation (103), and means for dispensing the release formulation (81-85) by positive displacement of a barrier material (98-102) by an expanding material (81-85) by application of heat from a resistive heating element (81'-85'). See Figs 7A and 7B.

Krulevitch does not disclose the material of the microneedles being made of a metal, or a rupturable metal foil covering over the distal end of the microneedles.

Gonnelli discloses a microneedle array which is covered by a membrane where the array is made of a biocompatible material (copper or gold, for example). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a membrane over the microneedles in order to prevent leakage of the reservoirs or contamination of the reservoir contents. Regarding claim 20, copper is considered "reactive." Regarding the defects to facilitate rupture, the bonding of the membrane layer would inherently create stress concentrations in the membrane along the edge of the microneedle. Claim 28 is a product by process claim which is given little patentable weight.

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4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch in view of Santini or Gonnelli as above, and further in view of Lee (US 5,911,737).

Krulevitch and Santini or Gonnelli discloses a micro needle array with a rupturable covering as disclosed above but does not disclose the use of a shape memory alloy in construction of the micro tube.

Lee teaches the use of a shape memory alloy in construction of a micro tube (Col 1 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the shape memory alloy of Lee with the micro tube array as an alternative material.

5. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch and Gonnelli as applied to claims 14 and 16 above, and further in view of Theeuwes (US 4,111,202).

Krulevitch and Gonnelli teach the limitations of claim 16 as above, but do not teach the use of a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation.

Theeuwes teaches an osmotic drug delivery system with a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation (Fig 4)

It would have been obvious to one of ordinary skill in the art at the time the invention

Was made to combine the osmotic delivery system of Theeuwes with the micro needle array of Krulevitch and Gonnelli in order to facilitate expansion of the expandable member without electronics.

***Response to Arguments***

6. Applicant's arguments with respect to claims 14-29, 35, 36, and 39-47 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1. The first group of people who are likely to be affected by the proposed project are the local residents who live in the vicinity of the project site. These residents may be affected by the project in a number of ways, including increased traffic, noise, and air pollution. The project may also affect the local economy by creating jobs and increasing the demand for goods and services. The project may also affect the local environment by increasing the demand for water and electricity and by increasing the amount of waste generated.